Management options in women with preterm uterine contractions: a randomized clinical trial

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Three management strategies (observation, intravenous hydration or 0.25g dose of subcutaneous terbutaline sulfate) for pregnant women with preterm uterine contractions were evaluated.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Pregnant women with preterm uterine contractions formed the study population. Eligible women had a singleton gestation between 20 and 34 weeks, intact membranes, more than three contractions in 30 minutes, and cervical dilation 1cm of less and effacement less than 80%.

Setting
The study appears to have been carried out at the Department of Obstetrics and Gynaecology at the University of Alabama, USA and the Copper Green Hospital, USA. It is not clear whether these two departments form the same establishment or whether two separate centres were involved in the study.

Dates to which data relate
The effectiveness data relate to the period September 1993 to May 1995. Dates were not given for resource use or prices.

Source of effectiveness data
The evidence on final outcomes was derived from a single study.

Link between effectiveness and cost data
Resource data relating to length of stay and number of admissions were prospectively collected from the same patient sample as that used in the effectiveness study.

Study sample
179 patients were randomised: 56 to observation, 62 to hydration and 61 to terbutaline. Consenting women were assigned to a treatment group by way of opening the next sealed, opaque envelope containing the computer-generated randomisation schedule. Sample size calculations were performed, revealing that each group would need to contain 53
patients in order to have a 90% chance of detecting an inter-group difference of at least one week in the number of days from randomisation to delivery. The number of women invited who refused to participate was not stated, and neither was the number of women who were not deemed eligible.

**Study design**
This study took the form of a randomised controlled trial. It is not clear whether this was a single centre trial or whether two centres were involved; if the latter is the case, results were not presented separately for each centre. Women with recurrent preterm uterine activity remained in their assigned group during subsequent triage visits. Women were followed up until delivery. No women were lost to follow-up.

**Analysis of effectiveness**
Intention to treat. All patients beginning treatment followed treatment through in their respective groups. The primary health outcomes were mean interval from randomisation to delivery (days), mean interval from randomisation to discharge (hours) and length of triage visit (hours). Groups were reported to be similar at randomisation with respect to maternal age, race, parity, history of prior preterm births, cervical status and contraction frequency.

**Effectiveness results**
There was no difference among the groups in terms of interval to delivery (p=0.69), however there was a statistically significant difference in the mean interval from randomisation to delivery (p=0.006) with women in the observation group remaining 5.2 hours, those in the hydration group 6 hours and those in the terbutaline group 4.1 hours. 79% of those in the terbutaline group had a triage visit of less than 4 hours compared with 64% in the observation group and 57% in the hydration group. 8% of women in the terbutaline group were admitted to hospital, as compared with 13% in the hydration and observation groups.

**Clinical conclusions**
There were no significant differences in the health outcomes of women randomised to observation, hydration or terbutaline.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used by the authors. Therefore the benefits were assumed to be equal to the effectiveness results and as such a cost-consequences analysis was performed.

**Direct costs**
The approximate cost of treatment and charges generated on the first visit for women observed for less than 48 hours were estimated. The number of patients in this part of the study consisted of 49 in the observation group, 55 in the terbutaline group and 54 in the hydration group. Quantities and costs were only analysed separately with regards to length of stay.

**Statistical analysis of costs**
Costs were treated in a stochastic way using the Kruskal-Wallis test for p values.

**Indirect Costs**
Indirect costs were not measured.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
There was a statistically significant difference (p=0.0001) in mean cost for the first triage visit of less than 24 hours with mean values of $207 in the observation group, $246 in the hydration group and $189 in the terbutaline group. The total cost of treatment among women discharged at less than 24 hours was $10,126 in the observation group, $10,396 in the terbutaline group and $13,277 in the hydration group (no data on significance).

Synthesis of costs and benefits
No synthesis of costs and benefits was undertaken.

Authors' conclusions
The authors concluded that there were no significant differences in the outcomes of women randomised to these 3 groups although treatment with one dose of subcutaneous terbutaline reduced the length of triage visits, resulting in lower costs without increasing morbidity. Intravenous hydration was associated with the highest costs and charges whilst also requiring the most intensive nursing support and having the highest potential for complications.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparators was clear; several different management strategies for the management of preterm uterine contractions are practised.

Validity of estimate of measure of benefit
The patients were randomised to management groups, the size of which were calculated according to power calculations. However larger groups would be necessary in order to detect smaller differences between management groups on the interval between randomisation and delivery. Groups were also reported to be similar in characteristics although it was not reported how many women declined the invitation to participate. No summary benefit measure was used in the economic analysis.

Validity of estimate of costs
Unfortunately few data were provided on the calculation of costs and the origin of the charges. Also, not all costs were taken into account and only the costs associated with a triage visit of less than 24 hours, on a subset of the patient sample, were measured.

Other issues
The study is useful in showing that there are unlikely to be large differences in the outcome of women managed according to these three strategies, although further, larger studies could be carried out to confirm this.

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